

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Alexander HILLISCH et al.

Serial No.: 10/631,967

Group Art Unit: 1617

Filed: 8/1/03

Examiner: Barbara Badio

For: PROGESTERONE RECEPTOR MODULATORS WITH INCREASED
ANTIGONADOTROPIC ACTIVITY FOR FEMALE BIRTH CONTROL AND HORMONE
REPLACEMENT THERAPY

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

- ☒ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
 - ☐ within three months of the actual filing date of the national phase of a PCT application; OR
 - ☒ before the mailing of a first substantive office action (including after filing of an RCE).
- ☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- a final rejection under 37 C.F.R. 1.113;
 - termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
 - a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
- ☐ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).

☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

- ☐ a final action under 37 C.F.R. § 1.113;
- ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2);
- ☐ OR a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. _____, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an international search report dated _____.
- ☐ Not required by 37 CFR § 1.98.

- ☒ Copies of the materials listed are attached (except for the foregoing).

Non-English Language References

- ☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
- ☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone
Y = document of particular relevance when it is combined with another such document
A = document defining the general state of the art
O = non-written disclosure
P = intercalated document
T = document cited to understand the theory or principle underlying the invention
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date
D = cited in the application
L = cited for another reason
& = publication of member of same patent family

- ☐ Translation of other relevant information on foreign search report

[insert necessary translation here]

CONCISE EXPLANATION OF RELEVANCE

AA: This application has US counterpart application US 2004/0092492 A1, At the filing date of the present application (August 1, 2003 in US) DE 102 21 034 was unpublished.

BB: The US counterpart is US 4,257,948. The invention relates to a novel epoxidation agent comprising H₂O₂ and hexachloracetone. It can be used to react with a steroid bearing at least one ethylenic unsaturation, and an epoxidised steroid is thus obtained.

The document is cited in connection with the preparation procedure of the compounds of formula I of the present application.

CC: This patent application has no counterpart anywhere. It describes 3-oxo-17 α -allyl-17 β -hydroxy-estra-4,9,11-triene as a new medicament. In the preparation of this compound 3,3-dimehoxy-estra-5(10),9(11)-dien-17-one is used which is also a starting compound in the

preparation of the compounds of the present invention.

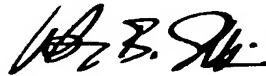
DD: This document describes the pentaerythritester as a pharmaceutical auxiliary substance. The document is cited with respect to the pharmaceutical formation of the compounds of the present invention.

EE: This is from Ullmann's Encyclopedia of Technical Chemistry, Volume 4, 1953 and describes technologies and vehicles and adjuvants suitable for the preparation of tablets, capsules, pills, etc.

Payment of Fees Due (If Any):

- ☐ A check for \$_____ covering the fee identified above is attached.
- ☐ Please charge to Deposit Account No. 13-3402 \$_____ for the fee identified above.
- ☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



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